4/27/99

K990422

510 (k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

FOR

BAUSCH & LOMB ReNu MultiPlus$_{TM}$ MULTI-PURPOSE SOLUTION

PROFESSIONAL LABELING

1. **Submitter Information**

Bausch & Lomb Incorporated
Global Vision Care
1400 North Goodman Street
Rochester, New York 14692-0450

Contact Person: Paul G. Stapleton
Director, Regulatory Affairs

Telephone Number: 716-338-8172

2. **Device Name**

Classification Name: Soft (hydrophilic) Contact Lens Solution

Proprietary Name: BAUSCH & LOMB ReNu MultiPlus Multi-Purpose Solution

3. **Predicate Devices**

Bausch & Lomb ReNu^{R} Multi-Purpose Solution has been selected as the predicate device for Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution, Professional Labeling.

4. **Description of the Device**

Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution is a sterile, isotonic solution that contains HYDRANATE^{TM} (hydroxyalkyl phosphonate) as a protein deposit remover, poloxamine as a surface active agent and salts as tonicity and buffering agents; preserved with DYMED^{R} (polyaminopropyl biguanide) 0.0001%. The product is indicated for use in the daily cleaning, removing protein deposits, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care practitioner. Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution is also indicated for use in the in-office chemical (not heat) disinfection of trial soft (hydrophilic) contact lenses. The sterile solution is contained in a plastic bottle and is labeled with a lot number and expiration date.

5. Indications for Use – Professional Labeling

Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution is indicated for use in daily cleaning, removing protein deposits, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care practitioner. It is also indicated for the in-office cleaning, rinsing and chemical (not heat) disinfection and storage of trial soft (hydrophilic) lenses for up to thirty (30) days.

6. Description of Safety and Substantial Equivalence

A series of preclinical and clinical studies were completed on this product and have previously been submitted under Premarket Approval Application P860023/ S12. No concerns were raised at the time of approval. In addition, ISO Stand Alone Procedure for Disinfecting Products was performed in glass vials to demonstrate the biocidal efficacy of ReNu MultiPlus Multi-Purpose Solution at thirty (30) days with and without lenses using S. aureus, Ps. aeruginosa, S. marcescens, C. albicans, and F. solani. The results met the primary performance criteria of the draft ISO/CEN Stand-alone Procedure for Disinfecting Products (March 23, 1995) and the draft Stand-alone Procedure for Disinfecting Products contained in the draft Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products (June 7, 1995). The ISO FDA Regimen Procedure for Disinfecting Regimens has been performed with Herpes simplex Virus, Type 1 and Adenovirus Type 7 with satisfactory results at thirty (30) days.

Substantial Equivalence

Bausch & Lomb ReNu MultiPlus Multipurpose Solution is substantially equivalent to Bausch & Lomb ReNu Multi-Purpose Solution for the in-office cleaning, rinsing and chemical (not heat) disinfection and storage of trial soft (hydrophilic) lenses for up to thirty (30) days.

The ReNu MultiPlus Multipurpose Solution will be sold in plastic bottles as a sterile solution; each bottle will be marked by a lot number and expiration date.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 1999

Mr. Paul G. Stapleton
Director, Regulatory Affairs
Bausch & Lomb
Global Vision Care
1400 N. Goodman St
Rochester, NY 14603-0450

Re: K990422
Trade Name: Bausch & Lomb ReNu MultiPlus ® Multi-Purpose Solution (for in office use with trial lenses)
Regulatory Class: II
Product Code: 86 LPN
Dated: February 10, 1999
Received: February 11, 1999

Dear Mr. Stapleton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K-990422

Device Name: **Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution**

Indications for Use:

Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution is indicated for use in daily cleaning, removing protein deposits, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care practitioner. It is also indicated for the in-office cleaning, rinsing and chemical (not heat) disinfection and storage of trial soft (hydrophilic) lenses for up to thirty (30) days.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use ✓

Mya Smith

(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K990422